

AMENDMENTS TO THE SPECIFICATION:

Please replace the paragraph beginning at page 1, line 3 with the following rewritten version:

-- This is a divisional application of Application No. 09/725,498, which was filed on November 30, 2000 and claims right of priority under 35 U.S.C. 119 to Japanese Patent Application 11-341085, filed on November 30, 1999. Certified copies of the priority documents have been filed in the Application No. 09/725,498. --.

Please replace the paragraph beginning at page 2, line 10 with the following rewritten version:

-- Both internal and external methods are utilized for quality control. Internal quality control is a method of assaying identical quality control substances daily with the same analyzer, and monitoring whether stable assay results are being obtained. External quality control is a method of monitoring whether assay results that are being obtained ~~that~~ are the same as results assayed by an identical analyzer employed outside those facilities. --

Please replace the paragraph beginning at page 4, line 1 with the following rewritten version:

-- Because assay is not possible while an analyzer is down, patient test results in clinical examination cannot be reported to the diagnosing physician. For samples like blood, which has with low preservation stability, delaying the assay by one ~~assaying the following~~ day would mean lower accuracy in the test results, and therefore blood has to be drawn from the patient again. --

Please replace the paragraph beginning at page 4, line 7 with the following rewritten version:

-- A second issue the invention addresses is that, with external quality control, as described above, confirmation can be obtained is only by waiting for the tally from the statistics center. This normally is done once a year, and at most on the order of only three or four times a year. --

Please replace the paragraph beginning at page 4, line 24 with the following rewritten version:

-- Wherein a substance such as blood that is liable to transform (denature) over time is the assay subject, the freshness of the quality control substance employed in the sample data assay must be at the same level among each of the facilities taking part in external quality control. When quality control substances are sent out to facilities to collect sample data, inevitably the assaying tends to be performed on different days at different facilities ~~have a propensity to be diverse. Accordingly, Herein,~~ because the freshness of the quality control substances that are the basis for the sample data collected tends to vary, the reliability of the tally results is diminished. --

Please replace the paragraph beginning at page 7, line 21 with the following rewritten version:

-- Accepting control operations from an information terminal even when ~~though~~ the information terminal is in a distant support center allows for the fast resolution of troubles. --

Please replace the paragraph beginning at page 8, line 21 with the following rewritten version:

-- In order that the tally results be on parameters in which the freshness of the quality control substances is alike, the statistical calculations (tallying) may be on sample data assayed within a predetermined timeframe, for example, within twenty-four hours of being received. When an analyzer requests tally results, the latest tally results at that point are provided in real time. In the present invention, communications by SMTP, which are ~~is~~ unlikely to be subject to the restrictions of firewalls, are preferable. --

Please replace the paragraph beginning at page 13, line 9 with the following rewritten version:

-- Fig. 20A is a conceptual explanatory diagram of tallying process wherein data from the past 24 hours are the tallying object, and Fig. 20B is a conceptual explanatory diagram of tallying process wherein data from the past 48 hours are the tallying object; --

Please replace the paragraph beginning at page 21, line 8 with the following rewritten version:

-- The user, after sample data assay, acquires the tally results that the control device 1 has tallied (#6) and confirms the external accuracy. The control device 1 updates the Web pages in accordance with updates to the tallied data. The analyzer 2 accesses a Web page, and when the access is authorized ~~authenticated~~, the latest tally results and the sample data are provided on the Web page. --

Please replace the paragraph beginning at page 23, line 23 with the following rewritten version:

-- In Step S4, the e-mail server 15 receives data from the analyzer 2. The processing unit 12 determines whether the received data is predetermined operational information or not. Operational information is predetermined information other than sample data, and includes, for example, error data, number of times operated, program log, and set-up information. If the answer is "yes," then Step S5 ensues; if "no," Step S7 ~~S6~~ ensues. --

Please replace the paragraph beginning at page 26, line 19 with the following rewritten version:

-- In Step S29, the processing unit 12 determines whether Step S23 through Step S28 have been performed for all registered analyzers 2. If "Yes," operations return to Step S21, and wait ~~that is, it waits~~ for the date to change. If "No," then operations return to Step S22, and choose ~~chooses~~ another analyzer as the subject user. --

Please replace the paragraph beginning at page 27, line 9 with the following rewritten version:

-- In Step S31, the processing unit 12 tallies sample data in which newly received sample data is included. Multiple varieties of quality control substances, such as those whose value is high and those whose is low, and those whose value is within a normal range and those whose value is within an abnormal range, are often employed in the same assay category. Wherein the quality control substance is from vital components, values from lot to

lot--that is, the lot number for each manufacturing instance--will routinely differ. Furthermore, assaying mode under which the sample data was assayed must be taken into consideration in order to determine correction values for the assayed data. The control substance type, lot number, and assaying mode are reported from the analyzer to the control device in a manner to be described later. --

Please replace the paragraph beginning at page 27, line 24 with the following rewritten version:

-- Statistical tallying is conducted for each sort of analyzer and for each kind of quality control substance. Because substances like blood, which are liable to change (denature in the case of blood) over time, are used as the quality control substance, tallies are made each ~~per~~ assay day to raise the reliability of the tally results. That the latest tally results are presented in real time in the present invention engenders the risk that the reliability of the tally results is not kept up during the ~~at an~~ early morning hours, ~~hour~~, ~~with~~ since the total count of sample data for that day's assays is ~~being~~ insufficient. Therefore, ~~Therein~~, the tally for that day's assays is made on sample data received, for example, within the past 24 hours. In this way, sample data from assaying conditions under the same elapsed-time changes can be employed, which prevents the total count from fluctuating markedly according to time slot. At the point the date changes, the tally results within the past 24 hours are set as the tally results for that day. --

Please replace the paragraph beginning at page 30, line 2 with the following rewritten version:

-- Fig. 7 is a flowchart showing one example of the flow of the main process performed by the analyzer. The analyzer 2 transmits error information and sample data in real time, and transmits operational information other than error information when the operations of the analyzer's ~~device~~ end. Fig. 7 shows only the flow according to the present invention. When the analyzer is activated, the following process commences. --

Please replace the paragraph beginning at page 31, line 5 with the following rewritten version:

-- In Step S46, the control unit 28 acquires sample data from the analysis unit 21 ~~control device 1~~ and processes it to be data for email. For example, it writes authentication information into the text of the email, and creates an email with the sample data ~~data~~ attached as a file attachment. Other information that is needed when analyzing sample data may be included in the file attachment[[],]. Such information includes, for example, lot number, type of quality control substance, assay mode, and device ID. Device ID is identification information for the purpose of identifying an analyzer on this system, and is used to prevent sample data from being entered more than once during analysis. --

Please replace the paragraph beginning at page 31, line 19 with the following rewritten version:

-- In Step S48, the control unit 28 awaits for operational information showing the operational conditions of the analysis unit 21 ~~control device 1~~ other than error information. Operational information other than error information can include number of times operated, operation program, set-up conditions and the like. When operational information arises, operations proceed to Step S49. In all other cases, the process flow proceeds to Step S41. --

Please replace the paragraph beginning at page 33, line 7 with the following rewritten version:

-- Fig. 9 shows an example of a screen displayed when "error log" has been selected on the operational information selection screen of Fig. 8. Error date and time, error message describing error, error code specifying error, and detailed code 1 and detailed code 2 are displayed. This error log displays, for example, the latest month worth of error log stored in the history database. It is preferable that it be possible to make settings for sorting ~~sort~~ and filtering ~~filter~~ for each field. It is also preferable that records of abnormalities that have a high possibility of being the cause of trouble be displayed in an easily distinguishable reverse display or the like. Records ~~Record~~ of abnormalities, for example, are records of occurrences where the above-described error level is ~~being~~ above a predetermined value. --

Please replace the paragraph beginning at page 35, line 9 with the following rewritten version:

-- In terms of internal quality control, ~~the as-is display of~~ displaying these assay values as they are allows confirmation of the fluctuations in sample data from an analyzer. In terms of external quality control, confirmation is possible of the fluctuations in the sample data from an analyzer against the overall average, using the overall average at the time of taking the sample data, as shown in Fig. 15. By changing the display as he sees fit, a user can make a visual comparison to see how much the sample data of the analyzer deviates from the overall average and the reference machine data. Furthermore, the Web pages on Fig. 14 and 15 are updated immediately after sample data has been submitted. Therefore, a user can perform external quality control for the sample data he has submitted in real time, without a time lag. --

Please replace the paragraph beginning at page 37, line 9 with the following rewritten version:

-- Analysis of sample data is conducted in the following way. In the same manner as the first embodiment, data collected in the past 48 hours is tallied, and those results become real time tally results. Alternatively, the tally results for each day are computed by tallying from among the data collected in the past 48 hours, including ~~that~~ data collected during the previous day. --

Please replace the paragraph beginning at page 37, line 20 with the following rewritten version:

-- However, when the reference time for analysis is set as local time, the reference time will differ from time zone to time zone, and thus analyses have to be conducted for each time zone. This means that there will be 24 different tally results across the world for a single date, making operation of the system complicated. On top of this, there are countries that have more than one time zones ~~zone~~, and group hospitals that are located across more than one time zones ~~zone~~. --

Please replace the paragraph beginning at page 38, line 15 with the following rewritten version:

-- In consideration of the above, in this embodiment, the reference time for the control device 1 is made to be the world's most advanced time, namely, GMT (Greenwich Mean Time) + 12 hours. In the explanation below, the reference for time of day is the time of day of the time zone in which the control device 1 is located, in this instance, the GMT + 12 hours time zone. Each analyzer 2 transmits to the control device 1, along with the sample data, the assay time and date in the time zone in which it is located. The control device 1 conducts analysis of the sample data based on sample data having an assay time and date within the past 48 hours. The reason for tallying sample data for the past 48 hours rather than the past 24 hours is to ensure that there will be a sufficient number of sample data sets N that will form the basis of the analyses. --

Please replace the paragraph beginning at page 39, line 18 with the following rewritten version:

-- Fig. 20A is an explanatory diagram showing there being an insufficient number of sample data sets N received in the past 24 hours. To facilitate the explanation, let us suppose that analyzers A, B, C, D, and E[[],] are located in different times, and transmit sample data daily at the local time of 00:00 in each time zone. Analyzer A is in the GMT + 12 hours time zone. Analyzer E is in the GMT - 12 hours time zone, and analyzers B, C, and D are in time zones in between. The control device is in the GMT + 12 hours time zone. --

Please replace the paragraph beginning at page 40, line 9 with the following rewritten version:

-- When the time for the control device is 00:00 on the 3rd day (time of day T1), A₂, B₂, C₂, D₂ and E₂ are included in the sample data from the past 24 hours. However, when a little time passes and the time of day becomes the time of day T2, all that is included in the sample data from the past 24 hours is the data in the shaded triangular region in the figure, that is, only A₃. In such a case, the further a time zone is from GMT + 12 hours, the greater the possibility that the sample data will not be tallied, meaning that there will be an insufficient number of data sets N and that it will be difficult to always provide reliable tally results. --

Please replace the paragraph beginning at page 40, line 21 with the following rewritten version:

-- Fig. 20B is an explanatory diagram showing there being a sufficient number of data sets N when the analysis is based on sample data received in the past 48 hours. When the time for the control devices reaches 00:00 on the 3rd (time of day T1), sample data from analyzers A through E dated the 1st and 2nd (A₁, B₁, C₁, D₁, E₁; A₂, B₂, C₂, D₂, E₂) are included within the sample data from the past 48 hours. Next, when a little time passes and the time of day becomes time of day T2, the data within the shaded trapezoidal region in the figure (i.e., A₂, B₂, C₂, D₂, and E₂) becomes the population for analysis. In actuality, while the assay time differs for each analyzer, by making the analysis population the sample data of the past 48 hours, ~~makes it is~~ possible to ensure that there is always a number of sample data sets close to the total number of analyzers on the system. If there is a plurality of sample data sets from the same analyzer within the population, all such sets other than the sample data set with the most recent assay time may be excluded from the analysis. --

Please replace the paragraph beginning at page 42, line 6 with the following rewritten version:

-- Fig. 21A is a drawing explaining the concept of a current-day's tallying process. In the current-day's tallying process, first preliminary population ~~populations~~ made up of sample data dated within the past 48 hours ~~is~~ are sequentially created, using ~~with~~ the time at ~~of~~ the control device 1 as the reference time. Furthermore, sample data analysis is conducted based on the first preliminary population, and the current-day's tally results are updated. In this embodiment, the updating ~~update~~ and tallying process of the first preliminary population is conducted every 10 minutes. --

Please replace the paragraph beginning at page 44, line 6 with the following rewritten version:

-- Fig. 21(b-1) shows a second preliminary population at time of day T3 (10:00 on the 3rd), 10 hours into the ~~after time of~~ day T2. Region S1' is a ~~that~~ group of sample data dated the 1st and having an assay time within 48 hours of T3. Region S2' is a group of sample data with an assay date of the 2nd that has already been collected. Region S3' is ~~that~~

sample data from the past 48 hours that is dated the 3rd and is to be deleted from the second preliminary population. At time of day T3, the control device computes the tally results for the previous day (the 2nd) based on the sample data from region S1' and region S2'. --

Please replace the paragraph beginning at page 44, line 17 with the following rewritten version:

-- Fig. 21(b-2) is the second preliminary population at a ~~the~~ point in time of ~~time of~~ day T4 (00:00 on the 4th), which is 24 hours after the time of day T2. The shaded region S2 indicates the second preliminary population at this point in time. The second preliminary population at this point in time comprises the group of sample data sets dated the 2nd from all the analyzers participating in the remote support system. At this point in time, the control device 1 finalizes the population for the analysis of the day two days prior (the 2nd). The tally results obtained from this population become the final tally results for the day two days prior (the 2nd). --

Please replace the paragraph beginning at page 48, line 21 with the following rewritten version:

-- Step S118: If it is determined at Step S111 that the date has changed, in other words, that the time of day has become 00:00 on the 4th, the control device 1 finalizes the population that will serve as the basis for the tally results of the 2nd. In other words, the second preliminary population at this point in time becomes the population for the tally results of the day two days prior (i.e., the 2nd). Only sample data dated the 2nd is contained in the finalized population [refer to Fig. 21(b-2)]. --

Please replace the paragraph beginning at page 49, line 5 with the following rewritten version:

-- Steps S119: The control device 1 computes the tally results for the day two days prior based on the finalized population. --